



## DrugCheck® Dip Drug Test

The **DrugCheck® Dip Drug Test** is an immunochromatographic assay for the qualitative detection of Opiates in human urine at a cutoff concentration indicated in the table below.

The test may yield preliminary positive results when prescription drugs are ingested at prescribed doses. It is not intended to distinguish between prescription use and abuse of any drug. There are no uniformly recognized cutoff concentration levels for any drug in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use and for professional testing use only.

### WHAT IS DRUGCHECK® DIP DRUG TEST?

The **DrugCheck® Dip Drug Test** is a rapid test for qualitative detection of Opiates in human urine. The **DrugCheck® Dip Drug Test** yields a positive result when drug and/or its metabolite in urine is at or exceeds its cutoff concentration.

### WHAT IS THE CUT-OFF VALUE?

Drug Test	Drug (Identifier)	Cut-off
Opiates (OPI300)	Morphine	300 ng/mL

### PRINCIPLE

The **DrugCheck® Dip Drug Test** is an immunoassay. During testing, a urine specimen migrates upward on the test strip. A drug-positive urine specimen will generate a colored line in the specific test line region of the strip, while a drug-negative urine specimen will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of specimen has been added.

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to individual drug on the list indicated in the table above.

### WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use and for professional testing use only.
- For external use only.
- For single use. Discard after first use.
- Do not use the test if the pouch is punctured or not well sealed.
- Do not use after expiration date.
- Keep out of the reach of children.
- The used dip test and urine specimen should be discarded according to federal, state and local regulations.

### CONTENT OF THE PACKAGE

Included in package:	Not included in package:
- User Instruction	- Watch, Timer or Clock
- Dip Test (inside foil pouch)	- Collection Cup

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4°C - 30°C. The test is stable through the expiration date printed on the sealed pouch. The dip test must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

### HOW TO COLLECT URINE FOR THE TEST?

You can use urine from any time of the day. The minimum detection time varies for different drugs.

### HOW TO COLLECT URINE?

- When you are ready to begin, remove the dip test from the sealed foil pouch.
- Notice the colored tape on each strip indicates the name of the drug you are testing for.
- Fill the collection cup with a fresh urine sample. Do not over-fill.

### HOW TO DO THE TEST?

#### For Single Dip Strip

- Insert the test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the conjugate pad on the strip, this could cause inconclusive drug test results. Place the test on a flat surface.
- Wait for 5 minutes (start timing immediately after dip is taken out of the urine sample). Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

#### For Single Dip Cassette

- Remove the cap from the dip test. Insert the exposed test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the plastic device, this could cause inconclusive drug test results.
- Insert the cap firmly back onto the dip test and lay it on a flat surface.
- Wait for 5 minutes (start timing immediately after dip test is taken out of the urine sample). Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

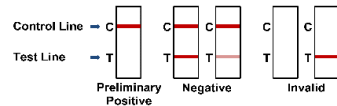
Note: Results after more than 5 minutes may not be accurate and should not be read.

### READING THE RESULTS

**Preliminary Positive (+):** If a line appears in the C - Control area but NO line appears in the T - Test area, then it indicates a Preliminary Positive result for the corresponding drug.

**Negative (-):** If a line appears in both the C - Control and T - Test area, then it indicates a Negative result for the corresponding drug regardless of how dark or light the line may appear.

**Invalid:** If at 5 minutes, NO line appears in the C - Control area, then the results are Invalid. In such case, retest with a new dip test.



**Note:** Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).

A positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

**IMPORTANT:** The result you obtained is called preliminary for a reason. The sample must be tested by a laboratory in order to determine if a drug of abuse is actually present.

### WHAT IS A FALSE POSITIVE TEST?

The definition of a false positive test would be an instance where the test result from the **DrugCheck® Dip Drug Test** is positive, even though the initial target drug is not present in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

### WHAT IS A FALSE NEGATIVE TEST?

The definition of a false negative test is that the initial target drug is present but is not detected by the **DrugCheck® Dip Drug Test**. If the sample is diluted, or if the sample is tainted or contaminated with a substance this could cause false negative results.

### TEST LIMITATIONS

- The **DrugCheck® Dip Drug Test** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- There is a possibility that interfering substances in the urine specimen may cause erroneous results.
- Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.
- A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

### QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be done with each new lot and each new shipment. It should be done every thirty days to check storage. Please contact our Technical Support at 507-526-3951 for controls that work with the dip test.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

In the comparison study, the **DrugCheck® Dip Drug Test** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for Opiates. Clinical specimens were quantified by GC/MS analysis before testing. The following results are tabulated from these clinical studies:

#### Accuracy – Opiates

Viewer A:

Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	0	13	26
Negative	10	10	20	1	0

% agreement among positives is 97.5%

% agreement among negatives is 100%

Viewer B:

Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Viewer C:

Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	0	13	26
Negative	10	10	20	1	0

% agreement among positives is 97.5%

% agreement among negatives is 100%

From the results of the above tables, the total results are shown as below for Opiates:

The average positive agreement is 97.5%.

The average negative agreement is 99.2%.

**Precision and Sensitivity – Opiates 300**

Lot 1

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	2/48
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	1/49
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	2/48
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

**Analytical Specificity**

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the **DrugCheck® Dip Drug Test** at a read time of 5 minutes.

Opiates 300	Result
(Morphine, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
6-Acetylmorphine	Positive at 750 ng/mL
Codeine	Positive at 300 ng/mL
Ethyl morphine	Positive at 200 ng/mL
Heroin	Positive at 700 ng/mL
Hydromorphone	Positive at 4,000 ng/mL
Hydrocodone	Positive at 2,000 ng/mL
Levorphanol	Positive at 12,000 ng/mL
Thebaine	Positive at 90,000 ng/mL
Methyprylon	Positive at 4,000 ng/mL
Morphine-3-β-D-Glucuronide	Positive at 450 ng/mL
Oxycodone	Negative at ≤ 10 <sup>5</sup> ng/mL
Procaine	Negative at ≤ 10 <sup>5</sup> ng/mL

**EFFECT OF URINARY SPECIFIC GRAVITY**

Urine samples of normal, high, and low specific gravity ranges (1.000-1.035) were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **DrugCheck® Dip Drug Test** was tested using twelve drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

**EFFECT OF URINARY PH**

The pH of an aliquot of negative urine pool was adjusted to pH ranges of 4.0 - 9.0 and spiked with drugs at 25% below and 25% above cut-off levels. The spiked, pH-adjusted urine was tested with the **DrugCheck® Dip Drug Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

**INTERFERENCE**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Opiates. The following compounds show no cross-reactivity when tested with the **DrugCheck® Dip Drug Test** at concentrations of 100 µg/mL.

Acebutolol	Erythromycin	Oxolinic Acid
Acetylpromazine-d6	β-Estradiol	Oxymetazoline
4-Acetamidophenol	Estrone-3-Sulfate	Hydroxymethamphetamine
Acetophenetidin	Ethyl-p-Aminobenzoate	Papaverine
N-Acetylprocainamide	2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine	Penicillin-G
Acetylsalicylic Acid	Fenoprofen	Pentobarbital
Aminopyrine	Furosemide	Perphenazine
Amitriptyline	Gentisic Acid	Phencyclidine
Amobarbital	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Phenobarbital
Ampicillin	Hydrochlorothiazide	Phentermine
Ascorbic Acid	Hydrocortisone	L-Phenylephrine
Amphetamine	o-Hydroxyhippuric Acid	β-Phenylethylamine
L-Amphetamine	3-Hydroxytyramine	Phenylpropanolamine
Apomorphine	Ibuprofen	Prednisolone
Aspartame	Imipramine	Prednisone
Atropine	Iprazid	Promazine
Benzilic Acid	(-)-Isoproterenol	Promethazine
Benzoic Acid	Isoxsuprine	DL-Propranolol
Benzoyllecgonine	Ketamine	D-Propoxyphene
Benzphetamine	Ketoprofen	D-Pseudoephedrine
Bilirubin	Labetalol	Quinidine
Brompheniramine	Loperamide	Quinine
Buprenorphine	Maprotiline	Ranitidine
Butalbital	Meprobamate	Salicylic Acid
Caffeine	Methadone	Secobarbital
Chloral Hydrate	Methamphetamine	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Methoxyphenamine	Sulfamethazine
Chlordiazepoxide	(±)-3,4-Methylenedioxy-amphetamine	Sulindac
Chlorothiazide	(±)-Chlorpheniramine	Tamazepam
Chlorpromazine	Methylenedioxy-methamphetamine	Tetracycline
Chloroquine	Methylphenidate	Tetrahydrocortisone 3-(β-D-Glucuronide)
Cholesterol	Nalorphine	Tetrahydrozoline
Clomipramine	Naloxone	Thiamine
Clonidine	Nalidixic Acid	Thioridazine
Cocaine Hydrochloride	Naltrexone	DL-Thyroxine
Cortisone	Naproxen	Tolbutamide
Creatinine	Niacinamide	Triamterene
Deoxycorticosterone	Nifedipine	Trifluoperazine
Dextromethorphan	Norcodeine	Trimethoprim
Diazepam	Norethindrone	Trimipramine
Diclofenac	D-Norpropoxyphene	Tryptamine
Diflunisal	11-nor-Δ <sup>9</sup> -THC-9-COOH	DL-Tryptophan
Digoxin	Nortriptyline	Tyramine
Diphenhydramine	Noscapine	DL-Tyrosine
Doxylamine	DL-Octopamine	Uric Acid
Ecgonine Hydrochloride	Oxalic Acid	Verapamil
Ecgonine Methyl Ester	Oxazepam	Zomepirac
(-)-ψ-Ephedrine	Oxycodone	

**BIBLIOGRAPHY OF SUGGESTED READING**

- Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
- Ambre J. J. Anal. Toxicol. 1985; 9:241.
- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

**ADDITIONAL INFORMATION AND REFERENCES**

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address, which can be accessed for additional information.















National Clearinghouse for Alcohol and Drug Information [www.health.org](http://www.health.org) 1-800-729-6686


Center for Substance Abuse Treatment [www.health.org](http://www.health.org) 1-800-662-HELP


The National Council on Alcoholism and Drug Dependence [www.ncadd.org](http://www.ncadd.org) 1-800-NCA-CALL

American Council for Drug Education (ACDE) [www.acde.org](http://www.acde.org) 1-800-488-DRUG

**SYMBOLS**

	Use-By Date		Manufacturer
	Catalogue Number		Temperature Limit
	Do Not Use if Package is Damaged		Do Not Re-Use
	Keep Away from Sunlight		Consult Instructions for Use
	Keep Dry		Caution
	Batch Code		In Vitro Diagnostic Medical Device
	Authorized representative in the European Community		Contains Sufficient for <n> Tests

 CareHeath America Corporation  
dba Express Diagnostics Int'l, Inc.  
1550 Industrial Drive  
Blue Earth, MN 56013

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3951 DB Maarn  
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